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May 15, 2002

VIA COURIER

The Commissioner of Patents
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Washington, D.C. 20231
United States of America

Dear Sirs:

RE: U.S. Patent Application No. 10/036,507
Filing Date: January 7, 2002
Applicant: Robert C. Brunham
**Title: DNA IMMUNIZATION AGAINST CHLAMYDIA
INFECTION**

Please find enclosed an Information Disclosure Statement and copies of the references listed therein with respect to each of the references cited in the specification, in the International Search Report received on the corresponding International application and in prior U.S. application No. 09/055,765.

Respectfully submitted,


Michael I. Stewart
Registration No. 24,973

M.I. Stewart/ac
Enclosure(s)

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Sheet 1 of 4

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 1038-1210 MIS:ac	SERIAL NO. 10/036,507
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		FILING DATE January 7, 2002	GROUP 1645

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U.S. PATENT DOCUMENTS

*INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUBCL.	FILING DATE
		5,589,466	Dec. 31, 1996	Felgner et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCL.	TRANSLATION
		0 192,033		EP			YES NO
		WO 98/02546	Jan. 22, 1998	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1.	Donnelly et al., Protective Efficacy of Intramuscular Immunization with Naked DNA Ann. N.Y. Acad. Sci. 772 (1995) pages 40-46 XP 000576178
2.	D. M. Pardoll and A. M. Beckerieg, Exposing the Immunology of Naked DNA Vaccines. Immunity 3, pp.165-169 (1995).
3.	W.M. McDonnell and F. K. Askari, Molecular Medicine DNA Vaccine. N. Engl. J. Med. 334, pp. 42-45 (1996).
4.	J. B. Ulmer et al., Heterologous Protection Against Influenza by injection of DNA Encoding a Viral Protein. Science Vol. 259, pp. 1745-1749 (1993).
5.	B. Wang et al., Gene inoculation generates immune responses against human immunodeficiency virus type 1. Proc. Natl. Acad. Sci. Vol. 90, pp. 4156-4160 (1993).
6.	G. J. M. Cox, T.J. Zamb, L.A. Babiuk, Bovine herpesvirus 1: Immune Responses in Mice and Cattle Injected with Plasmid DNA. J. Virol. Vol. 67, pp. 5664-5667(1993).
7.	E. Raz et al., Intradermal gene immunization: The possible role of DNA uptake in the induction of cellular immunity to viruses. Proc. Natl. Acad. Sci. Vol. 91, pp. 9519 -9523(1994).
8.	Z. Q. Xiang et al., Vaccination with a Plasmid Vector Carrying the Rabies Virus Glycoprotein Gene Induces Protective immunity against Rabies Virus. Virology Vol. 199, pp. 132-140 (1994).
9.	J.J.Donnelly et al., Protection against Papillomavirus with a Polynucleotide Vaccine. J. Infect. Dis. Vol. 713, pp. 314-320 (1996).
10.	D. L. Montgomery et al., Heterologous and Homologous Protection Against Influenza A by DNA Vaccination: Optimization of DNA Vectors. Cell. Biol. Vol. 12, pp. 777-783 (1993).
11.	J.J. Donnelly et al., Preclinical efficacy of a prototype DNA vaccine: Enhanced protection against antigenic drift in influenza virus. Nature Medicine Vol. 1, pp. 583-587 (1995).
12.	G. H. Rhodes et al., Characterization of Humoral Immunity after DNA Injection. Dev. Biol. Stand. Vol. 82, pp. 229-236 (1999).

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		FILING DATE January 7, 2002	GROUP 1645



OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

13.	H. L. Davis, M. L. Michel, R. G. Whalen, DNA-based immunization induces continuous secretion of hepatitis B surface antigen and high levels of circulating antibody. Human Mol. Genetics. Vol. 2, pp. 1847-1851 (1993).
14.	J. B. Ulmer et al., Protective immunity by intramuscular injection of low doses of influenza virus DNA vaccines. Vaccine Vol. 12, pp. 1541-1544 (1994).
15.	Z. Xiang and H. C. J. Ertl. Manipulation of the Immune Response to a Plasmid-Encoded Viral Antigen by Coinoculation with Plasmids Expressing Cytokines. Immunity Vol. 2, pp. 129-135 (1995).
16.	E. F. Fynan et al, DNA vaccines: Protective immunizations by parenteral, mucosal, and gene-gun inoculations. Proc. Natl. Acad. Sci. Vol. 90, pp. 11478-11482 (1993).
17.	E. Manickan, R. J. D. Rouse, Z. Yu, J. Genetic Immunization Against Herpes Simplex Virus. J. Immunol. Vol. 155, pp. 259-265 (1995).
18.	M. Sedegah, R. Hedstrom, P. Hobart, S. L. Hoffman, Protection against malaria by immunization with plasmid. DNA encoding circumsporozoite protein. Proc. Natl. Acad. Sci. Vol. 91, pp. 9866-9870 (1994).
19.	M.A. Barry, W.C. Lai, S.A. Johnston, Protection against mycoplasma infection using expression library immunization. Nature Vol. 377, pp. 632-635 (1995).
20.	D. Xu and F. Y. Liew, Genetic vaccination against leishmaniasis. Vaccine Vol. 12, pp. 1534 - 1536 (1994).
21.	D. B. Lowrie, R.E. Tascon, M. J. Colston, Towards a DNA vaccine against tuberculosis. Vaccine Vol. 12, pp. 1537-1540 (1994).
22.	J. W. Moulder, Interaction of chlamydia and Host Cells in Vitro. Microbiol. Rev. Vol. 55, pp. 143-190 (1991).
23.	J. Schachter, The Intracellular Life of Chlamydia. Curr. Top. Microbiol. Immunol, Vol. 138, pp. 109-139 (1988).
24.	S. D. Hillis and J. N. Wasserheit, Screening for chlamydia_ A key to the prevention of pelvic inflammatory disease. N. Engl. J. Med. Vol. 334, pp. 399-1401 (1996).
25.	R. C. Brunham and R. W. Peeling, Chlamydia trachomatis antigens: Role in Immunity and Pathogenesis. Infectious Agents and Disease Vol. 3, pp. 218-233 (1994).
26.	R. P. Morrison, D.S. Manning, H. D. Caldwell, Immunology of Chlamydia trachomatis infections:Immunoprotective and immunopathogenetic responses. Advances in Host Defence Mechanisms, T.C. Quinn, Ed. (Raven Press, New York, 1992), pp 52-84
27.	T. Grayston and S-P. Wang, The potential for Vaccine against Infection of the Genital tract with Chlamydia trachomatis. Sex Trans. Dis. Vol. 5, pp. 73-77 (1978).
28.	J.T. Grayston and S-P Wang, New knowledge of chlamydia and the diseases the cause. J. Infect. Dis. Vol. 132, pp. 87-105 (1975).
29.	H. R. Taylor, J. Whittum-Hudson, J. Schachter, et al. Oral immunization with chlamydia major outer membrane protein (MOMP) Invest. Ophthalmol. Vis. Sci. Vol. 29, pp. 1847-1853 (1988).
30.	B.E. Batteiger, R. G. Rank, P.M. Bavoil, et al., Partial protection against genital reinfection by immunization of guinea-pigs with isolated... J. Gen. Microbiol. Vol. 139, pp. 2965-2972 (1993).
31.	M. Campos et al., A chlamydia major outer membrane protein extract as a trachoma vaccine candidate. Invest. Ophthalmol. Vis. Sci. Vol. 36, pp. 1477-1491 (1995).
EXAMINER:	DATE CONSIDERED:

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

32.	H. Su, M. Parne, H. D. Caldwell, Protective efficacy of a parenterally administered synthetic olygopeptide... Vaccine Vol. 13, pp. 1023 -1032 (1995).
33.	T.- W. Tan, A.J. Herring, I. E. Protection of sheep against chlamydia psittaci infection with a subcellular vaccine.... Anderson, Infect. Immun. Vol. 58, pp. 3101-3108 (1990).
34.	M. Tuffrey, F. Alexander, W. Conlan, Heterotypic protection of mice against chlamydia salpingitis and colonization of the lower genital tract with a human... J. Gen. Microbiol. Vol. 138, pp. 1707-1715 (1992).
35.	Y. - X. Zhang, J. G. Fox, Y. Ho, Comparison of the major Outer-Membrane protein (MOMP) gene of mouse Pneumonitis. (MoPn) and ... Mol. Biol. Evol. Vol. 10, pp. 1327-1342 (1993).
36.	R. P. Morrison, K. Feilzer, D. B. Tumas, Gene Knockout mice establish a primary protective role for major histocompatibility..., Infect. Immun. Vol. 63, pp. 4661-4668 (1995).
37.	H. Su and H. D. Caldwell, CD4+T Cells play a significant role in adoptive immunity to Chlamydia Trachomatis infection of the mouse genital tract. Infect. Immun. Vol. 63, pp. 3302-3308 (1995).
38.	J. U. Igietseme et al., Resolution of Murine Chlamydial Genital infection by the adoptive transfer of a Biova-Specific, TH ₁ Lymphocyteclone. Reg. Immunol. Vol. 5, pp. 317-324 (1993).
39.	J. U. Igietseme and R. G. Rank, Susceptibility to refection after a primary chlamydial genital infection is associated with a decrease of..., Infect. Immun. Vol. 59, pp. 1346-1351 (1991).
40.	D. M. Williams, J. Schachter, J.J. Coalson, Cellular immunity to the Mouse Pneumonitis Agent. J. Infect. Dis. Vol. 149, pp. 630-639 (1984).
41.	G. Tipples and G. McClarty, Cloning and Expression of the Chlamydia trachomatis Gene for CTP Synthetase. J. Biol. Chem. Vol. 270, pp. 7908-7914 (1995).
42.	X. Yang, K. T. HayGlass, R.C. Brunham, Genetically Determined Differences in IL-10 and IFN Response correlate with Clearence..., J. Immunol., Vol. 156, pp. 4338-4344 (1996).
43.	H. Su and H. D. Caldwell, Kinetics of Chlamydia antigen processing and presentation to T Cells by Paraformaldehyde-Fixed Murine Bone Marrow-Derived Macrophages. Infect. Immun. Vol. 63, pp. 946-953 (1995).
44.	A. S. McWilliam, D. Nelson, J.A. Thomas, Rapid dendritic cell recruitment is a Hallmark of the acute inflammatory response at mucosal surfaces. J. Exp. Med. Vol. 179, pp. 1331-1336 (1994).
45.	M. R. Neutra, E. Pringault, J.-P. Kraehenbuhl, Antigen sampling across epithelial barriers and induction of mucosal immune responses. Annu. Rev. Immunol. Vol. 14, pp. 275-300 (1996).
46.	J.M. Austyn, New insights into the mobilization and phagocytic activity of dendritic cells. J. Exp. Med. Vol. 183, pp. 1287-1292 (1996).
47.	R. Brunham et al., Chlamydia trachomatis from individuals in sexually transmitted disease Core Group Exhibit frequent sequence variation in the major outer membrane protein. J. Clin. Invest. Vol. 94(1) , pp. 458-463 (1994).
48.	R. C. Brunham et al., The epidemiology of Chlamydia trachomatis within sexually transmitted diseases core group. J. Infect. Dis. Vol. 173, pp. 950-956 (1996).
49.	Tang et al., Genetic immunization is a simple method for eliciting an immune response. Nature 1992, 356: pp. 152-154.

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 5%;">50.</td><td>Davis L.H. et al., Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen. Vaccine (1994) Vol. 12 : 1503-1509.</td></tr> <tr><td>51.</td><td>Holland M. J. et al., Synthetic peptides based on Chlamydia trachomatis antigens identify cytotoxic T lymphocyte responses in subjects from a trachoma-endemic population. Clin. Exp. Immunol 1997 Jan; 107 (1): 44-49.</td></tr> <tr><td>52.</td><td>Su, H. et al, Identification and characterization of T-helper cell epitopes of the major outer membrane protein of Chlamydia trachomatis, J. Exp. Med. 1990 July 1: 172 (1): 203-212.</td></tr> <tr><td>53.</td><td>Su, H et al, Immunogenicity of a chimeric peptide corresponding to T helper and B cell epitopes of the Chlamydia trachomatis major outer membrane protein, J. Exp. Med. 1992, Jan.1; 175 (1): 227-235.</td></tr> <tr><td>54.</td><td>Allen, J. E. et al A single peptide from the major outer membrane protein of Chlamydia trachomatis elicits T cell help for the production of antibodies to protective determinants. J. Immunol. 1991, July 15; 147 92; 674-679</td></tr> <tr><td>55.</td><td>Knight, S.C. et al. A peptide of Chlamydia trachomatis shown to be a primary T-cell epitope in vitro induces cell-mediated immunity in vivo. PMID: 1712817, UI:91302820, Immunology 1995, May 15, 85(1), pages 8-15.</td></tr> <tr><td>56.</td><td>Lopez-Macia et al., "Induction of antibodies against Salmonella Typhi OmpC Porin by naked DNA immunization" Annals of the New York Academy of Science, Vol. 772, pp. 129-135, (1995).</td></tr> <tr><td>57.</td><td>Green, S. et al., Liposomal Vaccines. Immunobiology of Proteins and Peptides. VIII, (1995), pp. 83-92.</td></tr> <tr><td>58.</td><td>Zhang, D-J, et al., Intramuscular Immunization with a DNA Vaccine Produce Partial Immunity to Chlamydia trachomatis infection.(1997) pp. 113-117.</td></tr> <tr><td>59.</td><td>M.. Liu, M.R. Hilleman et al., Overview of DNA Vaccines. N.Y. Acad. Sci. Vol. 772, pp. 15-20 (1995).</td></tr> <tr><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td></tr> <tr> <td>EXAMINER:</td> <td colspan="3">DATE CONSIDERED:</td> </tr> </table>				50.	Davis L.H. et al., Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen. Vaccine (1994) Vol. 12 : 1503-1509.	51.	Holland M. J. et al., Synthetic peptides based on Chlamydia trachomatis antigens identify cytotoxic T lymphocyte responses in subjects from a trachoma-endemic population. Clin. Exp. Immunol 1997 Jan; 107 (1): 44-49.	52.	Su, H. et al, Identification and characterization of T-helper cell epitopes of the major outer membrane protein of Chlamydia trachomatis, J. Exp. Med. 1990 July 1: 172 (1): 203-212.	53.	Su, H et al, Immunogenicity of a chimeric peptide corresponding to T helper and B cell epitopes of the Chlamydia trachomatis major outer membrane protein, J. Exp. Med. 1992, Jan.1; 175 (1): 227-235.	54.	Allen, J. E. et al A single peptide from the major outer membrane protein of Chlamydia trachomatis elicits T cell help for the production of antibodies to protective determinants. J. Immunol. 1991, July 15; 147 92; 674-679	55.	Knight, S.C. et al. A peptide of Chlamydia trachomatis shown to be a primary T-cell epitope in vitro induces cell-mediated immunity in vivo. PMID: 1712817, UI:91302820, Immunology 1995, May 15, 85(1), pages 8-15.	56.	Lopez-Macia et al., "Induction of antibodies against Salmonella Typhi OmpC Porin by naked DNA immunization" Annals of the New York Academy of Science, Vol. 772, pp. 129-135, (1995).	57.	Green, S. et al., Liposomal Vaccines. Immunobiology of Proteins and Peptides. VIII, (1995), pp. 83-92.	58.	Zhang, D-J, et al., Intramuscular Immunization with a DNA Vaccine Produce Partial Immunity to Chlamydia trachomatis infection.(1997) pp. 113-117.	59.	M.. Liu, M.R. Hilleman et al., Overview of DNA Vaccines. N.Y. Acad. Sci. Vol. 772, pp. 15-20 (1995).																									EXAMINER:	DATE CONSIDERED:		
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